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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,176	04/23/2001	Joseph P. Dougherty	13257-00040	2969

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LICATA & TYRRELL P.C.
66 EAST MAIN STREET
MARLTON, NJ 08053

EXAMINER	
WOITACH, JOSEPH T	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,176	DOUGHERTY ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *7 and 8* is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *4/23/2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 29, 2005 has been entered.

DETAILED ACTION

This application is 371 national stage filing of PCT/US99/25477, filed October 29, 1999, which claims benefit to provisional application 60/106,533, filed October 31, 1998.

Applicants' amendment filed November 25, 2005, has been received and entered. Claims 1 and 2 have been amended. Claims 4-6 and 9-19 have been cancelled. Claims 1-3, 7 and 8 are pending.

Election/Restrictions

Applicant's election of Group I, was acknowledged. The election was treated as an election without traverse because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, (MPEP § 818.03(a)). No new arguments are presented

Claims 4-6 and 9-19 drawn to nonelected inventions have been canceled.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-3, 7 and 8 are under examination as they are drawn to the elected invention of a composition comprising transduced myeloid committed stem cells and a method of use to express an exogenous nucleic acid sequence.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendment to the claims to indicate that the "myeloid-committed stem cells" are "obtained from spleen" has addressed the basis of the rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

Specifically, the amendment to delete the term "spleen-derived" previously considered new matter has addressed the basis of the rejection.

Claims 1 and 2 (and dependent claim 3) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". In this case, the amendment and recitation of "wherein said composition is deficient of T-cells". Applicants do not point to any specific portion of the specification for support of the amendment. Review of the specification fails to provide literal support for the amendment, and the specification provides general support for compositions where the stem cells can be obtained from the spleen, however fail to provide any specific description of what would be contained in the composition, in particular the exclusion of any one cell type like T-cells now claimed. Example II provides for "[E]nriched B cells populations" by deleting T-cells, but fails to support the breadth of the claims for a myeloid-committed stem cells, rather it supports methods for isolating B-cells which are not myeloid committed stem cells.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described. As discussed above, the present specification provides for the isolation of a pluripotent cell from the spleen, however fails to provide any other methodology or a detailed characterization of the claimed cell. While the artisan may be capable of removing T cells from given a population, there is no guidance in the specification to this end for the isolation of a myeloid-committed stem cell, nor why or how this is excluded when processing cell samples from the spleen. In this case, the resulting population supported by the present specification would be B-cells.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to

determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 stand rejected under 35 U.S.C. 102(b) as being anticipated by Freas-Lutz DL *et al.* (Exp Hematol. 1994 Aug;22(9):857-65).

Claims 1 and 2 stand rejected under 35 U.S.C. 102(b) as being anticipated by Migita *et al.* (PNAS 92:12075-12079).

Applicants summarize the teaching of Freas-Lutz DL *et al.* and Migita *et al.* (page 9) and argue that the claims encompass cells with phenotypes that are not consistent with the cells disclosed in either Freas-Lutz DL *et al.* or Migita *et al.* See Applicants' amendment, bridging pages 8-9. Applicants arguments have been fully considered, and found persuasive in part.

Examiner would acknowledge that the process of isolating cells in the cited references and that presently disclosed are not the same, however would maintain that neither the specification nor the claims provides for more than the functional limitation that the myeloid committed stem cell is capable of differentiating into myeloid lineages. Applicants do not contest that the cells taught in Freas-Lutz DL *et al.* and Migita *et al.* do not have this capability, rather only that the cells would be different without indicating any functional difference or

characteristic the artisan would use for this distinction. Applicants argue that all the features now claimed are not taught, however it is not clear what these properties or features would be. Given the breadth of the claims in light of the teaching of the specification. Again, the present specification does not provide any specific definition for what is encompassed by the term myeloid committed stem cell, and therefore it has been given its broadest reasonable interpretation. In this case, cells Freas-Lutz DL *et al.* and Migita *et al.* meet this functional requirement. As noted previously, Freas-Lutz *et al.* teach the use of retroviral vectors for the transfection and expression of an exogenous nucleic acid sequence encoding glucocerebrosidase into the isolated cells. Further, the various retroviral constructs taught have various promoters to analyze the expression and activity of glucocerebrosidase , including the use of the phosphoglycerate gene promoter which is expressed in macrophages (a differentiated myeloid cell). Since the instant specification does not specifically define what a myeloid committed stem cell is, and in the broadest reasonable interpretation of being any cell with a restricted ability to become a differentiated cell of the myeloid lineage. Similarly, Migita *et al.* teach the use of retroviral vectors for the transfection and expression of an exogenous nucleic acid sequence encoding glucocerebrosidase. One of the cell types used by Migita *et al.* are human CD34+ cells (see top of page 12078, for example) which represent a population of cells which have the capacity to differentiate into various cells of the myeloid lineage. As discussed above, the instant specification does not specifically define what a myeloid committed stem cell is, and is being given the broadest reasonable interpretation of being any cell with a restricted ability to become a differentiated cell of the myeloid lineage. The CD34+ cells taught by Migita *et al.*

meet this interpretation of a myeloid committed progenitor cell because it is capable of myeloid specific differentiation.

Conclusion

Claims 7 and 8 are allowed.

While myeloid committed cells were known to be present in the spleen as early as 1982 in the prior art (see Magli *et al.* Nature, 1982), they represented a non-renewable and short lived source of such a cell type as summarized in the instant specification (age 2, lines 25-33). There is insufficient motivation in the art of record to use the spleen as a source of myeloid committed stem cells in methods of expressing myeloid specific proteins.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach